REMARKS

Claims 1, 2, 4, and 5 were pending at the time of the electronic mailing of the outstanding Office Action. By this amendment, claim 1 has been amended to recite the presence of first and second polymer carriers, which have differing degradation properties. Support for this amendment and for new claim 15 may be found in the specification in paragraphs 0054 and 0055 and in Figure 3a. New claims 16 and 17 have also been added. Claim 16 recites a stent having a coating system with first and a second pharmaceutically active substances, and where a concentration of the first pharmaceutically active substance is greater adjacent the face surfaces than in a middle portion of the stent, and the concentration of the second pharmaceutically active substance is greater in a middle portion of the stent than adjacent the face surfaces. Support for new claims 16 and 17 may be found in the specification in paragraph 0057, Figure 4 and original claim 2. Claim 5 has been cancelled without prejudice or disclaimer as to the subject matter contained therein.

In the Office Action of 9 July 2009, claims 1 and 2 were rejected under 35 U.S.C. § 103(a), as being unpatentable over U.S. Patent No. 7,169,178 to Santos et al. (hereinafter "Santos") in view of U.S. Patent No. 5,464,450 to Buscemi. Under 35 U.S.C. § 103(a), claims 4-5 were also rejected as being obvious over Santos in view of U.S. Pat. No. 5,972,027 to Johnson (hereinafter "Johnson").

In the Office Action, Santos is cited as providing a stent comprising a basic tubular body with a coating system comprising a polymer carrier and a pharmaceutically active substance, wherein a concentration of the pharmaceutically active substance varies in the

longitudinal direction of the stent. Santos is also indicated to teach a biodegradable coating material. It was alleged that the use of the degradation characteristics of the polymer to differentiate local elution characteristics would have been inherent in the disclosure of Santos, or that such a use would have been obvious to one of ordinary skill in the art at the time of the invention. Buscemi was alleged to teach the use of degradable stent materials, where the drugs are released as the material degrades at rates controlled by the rate of degradation.

As indicated above, claim 1 has been amended to recite the presence of first and second polymer carriers, which have differing degradation properties and those differences influence the elution characteristics at different positions on the stent. The Applicants maintain that neither Santos nor Buscemi teach or suggest such a stent. Santos provides a stent having a coating which carries a drug in which the concentration of the drug increases from one end to the other (column 2, lines 58-67), a stent in which the drug concentration varies circumferentially to specifically treat one side of a lumen with a greater concentration of drug (column 3, lines 1-3 and column 4, lines 43-50), and a stent in which a drug concentration is greater in a curved section of a stent than in a linear segment of a stent (column 3, lines 5-11).

Additionally, Santos devotes entire sections of the disclosure to "Methods of Varying Drug Concentration" (column 5, line 45 – Column 7 line 45) and "Methods of Varying the Release Rate" (column 7, line 48 – column 8, line 56). Clearly, Santos devotes significant consideration to the delivery of differing amounts of a drug in different portions of a stent, specifically mentioning varying the thickness of the polymeric coating, or including a diffusion

barrier layer. Santos discloses only the adjustment of diffusion rates, not degradation rates, to regulate the release of a drug from a stent (column 8, lines 43-57).

Because Santos does not teach or suggest the use of polymers with differing degradation rates to adjust the rate of drug delivery as recited in claim 1, the Applicants maintain that claims 1 and 2 (as well as 4 and 15, which depend from claim 1) patentably distinguish over Santos in view of Buscemi. Withdrawal of the rejection of claims 1 and 2 under 35 U.S.C. § 103(a) is respectfully requested.

Claims 4-5 were rejected under 35 U.S.C. § 103(a) as being obvious over Santos in view of Johnson. Claim 5 has been cancelled without prejudice and new claims 16 and 17 have been added. Claim 16 recites a stent having a coating system with first and a second pharmaceutically active substances, where the concentration of the first pharmaceutically active substance is greater adjacent the face surfaces than in a middle portion of the stent, and the concentration of the second pharmaceutically active substance is greater in a middle portion of the stent than adjacent the face surfaces.

In response to the Applicants' previous argument that combining Johnson with Santos would impermissibly change a principle of operation of Johnson, it was stated that the test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art, not whether the features of the secondary reference may be incorporated into the structure of the primary reference. However, the Applicants maintain that combining the teachings of the cited references and simultaneously changing a principle of

operation of one of those references to attempt to establish obviousness indicates that the proposed combination is nonobvious. Stated differently, needing to change a principle of operation when making such a combination to arrive at the claimed invention would tend to indicate that the combined teachings would not have suggested the present invention to one of ordinary skill in the art.

It should also be remembered that to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. There must also be a reasonable expectation of success and the prior art reference or references must teach or suggest all of the claim limitations. (MPEP § 2143.) Combining references that also require a change in a principle of operation of one of the references indicates that the references do not teach or suggest all the limitations of the claims, as required. As indicated previously, Johnson provides different concentrations of a drug in different areas of the stent based on the porosity of the stent material itself, not on the degradation behavior of a polymer. Johnson provides no indication that degradation plays any role in the release of a therapeutic agent. Therefore, claim 4 and new claims 15-17 patentably distinguishes over Santos and Johnson. Withdrawal of the rejection of claim 4 under 35 U.S.C. § 103(a) is respectfully requested.

In light of the arguments provided above, the Applicants maintain that the pending claims distinguish over the cited prior art. The issuance of a Notice of Allowance is respectfully requested.

The outstanding Office action was transmitted on 9 July 2009. The Examiner set a shortened statutory period for reply of 3 months from the mailing date. Therefore, no petition for an extension of time is believed to be required with the filing of this response. Nevertheless, the Applicants hereby make a conditional petition for an extension of time for response in the event that such a petition is required. No fees are believed to be due with this response. However, in the event that a fee for the filing of his response is insufficient, the Commissioner is authorized to charge any fee deficiency or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

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